K072308

510(k) SUMMARY

SUBMITTER:	Sorin Group Italia S.r.l. 86, Via Statale 12 Nord 41037 Mirandola (MO) Italy
CONTACT PERSON:	Luigi Vecchi Phone: 011 39 0535 29811 Fax: 011 39 0535 25229
DATE PREPARED:	August 16, 2007
DEVICE TRADE NAME:	D131 Dideco Kids Infant Arterial Filter with 40 micron screen phosphorilcholine (Ph.I.S.I.O.) coated (hereafter referred to as D131 Ph.I.S.I.O.)
COMMON NAME:	Arterial Filter
CLASSIFICATION NAME:	Cardiopulmonary Bypass Arterial Line Blood Filter
LEGALLY MARKETED UNMODIFIED DEVICE	D736 MICRO 40 Ph.I.S.I.O.: Dideco Newborn-Infant Arterial Filter with Ph.I.S.I.O. coating (Phosphorilcholine coating) as described in K002493 and modified in K033987
PREDICATE DEVICE:	D130 Dideco Kids Newborn Arterial Filter with 40 micron screen phosphorylcholine (Ph.I.S.I.O.) coated (hereinafter referred to as D130 Ph.I.S.I.O.) originally cleared for use with a maximum blood flow rate of 0.7 l/min under K063255 is manufactured by Sorin group Italia S.r.l.

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DEVICE DESCRIPTION:

The D131 Ph.I.S.I.O. is a sterile, non-pyrogenic disposable filter for use in arterial line of the cardiopulmonary bypass circuit with the flow rate not exceeding 2.5 liters/minute. The D131 Ph.I.S.I.O. is a Infant Arterial Filter with a 40 micron filter screen designed to remove potentially harmful gaseous emboli, aggregated blood constituents, and particulate debris greater than 40 microns from the arterial line perfusate. The overall dimensions have been reduced in the modified version of the D736 Ph.I.S.I.O. unmodified device resulting in decreased priming volume and surface area of the filtering material. The internal modifications which mainly involve the filter screen geometry, make the new filter essentially a downscaled and simplified version of the D736 Ph.I.S.I.O.. The modifications to some of the external features result in enhanced ergonomics.

INDICATION FOR USE:

The D131 Dideco Kids with 40 micron screen phosphorilcholine (Ph.I.S.I.O.) coated is recommended for use in the arterial line of the extracorporeal circuit during any procedure that requires cardiopulmonary bypass. The filter is used to trap and remove gaseous emboli as well as particulate debris that maybe introduced through the arterial line. The device should not be used longer than 6 hours. Contact with blood for longer periods is not advised.

TECHNOLOGICAL CHARACTERISTICS:

The D131 Ph.I.S.I.O. has the same operating principles and control mechanisms when compared to the D736 Ph.I.S.I.O. unmodified device and D130 Ph.I.S.I.O. predicate device. The D131 Ph.I.S.I.O. utilizes the

same materials, the same filtering media, the same main blood flow path and the same filtering pore size (40 micron) as both the unmodified and predicate devices.
The design features of the D131 Ph.I.S.I.O. have been updated with respect to those of the current D736 Ph.I.S.I.O. Newborn-Infant unmodified device. In addition, the D131 Ph.I.S.I.O. shares essentially the same basic design philosophy and geometry with the D130 Ph.I.S.I.O. predicate device. No change of the intended use has been made for the modified version of the device. Both devices share the identical manufacturing process. The arterial filter is ethylene oxide sterilized and has a nonpyrogenic fluid path. It is for single use only.

BIOCOMPATIBILITY TEST RESULTS:

As no new materials are used into the D131 Ph..S.I.O. infant arterial filter as compared to the D130 Ph.I.S.I.O. predicate device, data collected on aged D130 Ph.I.S.I.O. samples (K063255) are considered applicable also to the D131 Ph.I.S.I.O. modified device. A complete battery of tests were conducted in accordance with the requirements of ISO 10993-1:2002 and the FDA May 1, 1995 Memorandum on the use of the ISO 10993 standard for biocompatibility testing on the raw materials. Testing was performed on the D 130 Ph.I.S.I.O. (accelerated aging). The results of the testing met established specifications.

***IN VITRO* TEST RESULTS:**

In vitro testing was carried out in accordance with the relevant requirements of "Guidance for Cardiopulmonary Bypass Arterial Line Blood Filter 510(k) Submission" Final Guidance for Industry, dated November 29, 2000 for providing the data necessary to demonstrate both substantial equivalence with the unmodified device and show that the device is compliant with safety and effectiveness requirements. The device was aged up to 3 years (+ 1 additional year of aging in order to test a truly worst case) and tested for operating blood volume, structural integrity test, pressure integrity test, pressure drop, filter flow rate capacity, *in vitro* hemolysis/cell depletion, filtration efficiency, leaching of the coating and air handling characteristics. For comparative purposes all tests, when applicable, were performed on sterilized aged devices comparing the D131 Ph.I.S.I.O. vs. the D736 Ph.I.S.I.O. operated at same max blood flow. The results of these tests met established specifications..

CONCLUSIONS:

The results of *in vitro* studies demonstrate that the design modifications result in reduced priming volume and pressure drop with an effective filter flow rate capacity at all blood flow rates as compared to the D736 Ph.I.S.I.O. unmodified device. Both filters demonstrated a comparable structural integrity, hemolysis/cell depletion at the maximum blood flow. Both devices share similar removal capability for microbubbles as well as air bolus introduced in the circuit at minimum, mean and maximum blood flow tested. Likewise both filters demonstrated comparable filtration efficiency with an overall mean percent removal greater than 80% for particles equal to the nominal pore size of the filter (40μ). The D131 Ph.I.S.I.O. filter demonstrated integrity when pressurized over the maximum recommended pressure and no analytical evidence of the possibility of leaching of phosphoriylcholine coating from the D131 Ph.I.S.I.O. was evidenced during the leaching test. The results are in line with expectations because the D131 Ph.I.S.I.O. is smaller in overall size, has a more compact design, and contains a different filter screen design as compared to the unmodified device. The smaller size offers theoretical advantages in terms of reduced priming volume and consequently less hemodilution. A lower priming volume is desirable as it results in advantageous patient hemodynamics, reduced exposure of the blood cells and plasma proteins to large surface areas.
Biocompatibility tests demonstrate that its performance is equivalent to the D736 Ph.I.S.I.O. unmodified device, according to its intended use. Additional testing has demonstrated the effectiveness of production techniques assuring that the newborn arterial filter is sterile and non-pyrogenic
In conclusion test result of this study suggests the D131 Ph.I.S.I.O. arterial filter is equivalent to the D736 Ph.I.S.I.O. arterial filter with respect to device function.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Rockville MD 20850

Sorin Group Italia S.R.L
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SEP 12 2007

Re: K072308
D131 Ph.I.S.I.O. Dideco Kids Infant Arterial Filter
Regulation Number: 21 CFR 870.4260
Regulation Name: Cardiopulmonary bypass arterial line blood filter
Regulatory Class: Class II
Product Code: DTM
Dated: August 16, 2007
Received: August 17, 2007

Dear Mr. Sall:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SORIN GROUP
AT THE HEART OF MEDICAL TECHNOLOGY

Sorin Group Italia S.r.l.

510(k) Number (if known): K072308

Device Name: D131 Dideco Kids Infant Arterial Filter with 40 micron screen phosphorylcholine (Ph.I.S.I.O.) coated

Indications For Use:

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Prescription Use__ X ___ and/or Over-The-Counter Use___
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K072308